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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,118	03/29/2000	Harry Dugger III	PHCO3.0-008	7521
20582	7590	05/16/2005	EXAMINER	
JONES DAY 51 Louisiana Aveue, N.W WASHINGTON, DC 20001-2113			HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/537,118

Applicant(s)

DUGGER, HARRY

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-34, 54-59 and 80-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-34, 54-59 and 80-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/05 & 02/05.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 05/11/05.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after **non-final** rejection. Since this application is **not** eligible for continued examination under 37 CFR 1.114, Applicant's submission filed on 01/12/05 has **not** been entered.

Receipt is acknowledged of the amendments and remarks filed on 01/12/05 and 05/06/05. According to the amendments of 05/05/05, claims 1-26, 35-53 and 60-79 are cancelled, claims 27-34, 54-59 are amended and new claims 80-82 are added. Accordingly, claims 27-34, 54-59 and 80-82 are pending.

NOTE: The new claims and the amended claims are drawn to a method of administering a formulation comprising a solvent and an active agent. The elected claims after Election/Restriction requirements of 11/01/02 were drawn to a "propellant-free" composition. Thus the pending claims are considered to encompass a non-elected subject matter, propellant-containing formulations. For the purposes of examination, the claims are examined to the scope of a propellant-free formulation. Corrections are required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-34, 54-59 and 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deihl (WO 9413280) in view of Fassberg et al (EP 0656206A1).

Deihl teaches a sprayable analgesic composition comprising an analgesic compound which is absorbed into the bloodstream through the buccal mucosa and a pharmacologically acceptable liquid carrier. In a preferred embodiment the active agent is ibuprofen and the liquid carrier is aqueous ethanol (see page 3). The formulation may also contain other ingredients such as surfactants, humectants, flavoring agents, etc (see page 4). The table in example I shows the concentration ranges of each ingredient. Deihl fails to disclose other suitable active agents for the said formulation, or the use of other solvents including polyethylene glycol and non-polar solvent.

Fassberg discloses aerosol, formulations for oral or nasal administration, which comprise a medicament, an excipient, propellant and optionally surfactants. The suitable excipients include alcohols, polyethylene glycols, short chain fatty acids, etc (see page 3). Fassberg discloses that any pharmaceutically active agent which can be delivered by oral or nasal inhalation may be used. Examples include antihistamines, antiallergics, analgesics, antibiotics, steroids, bronchodilators, antihistamines, etc (see page 5, lines 42-50).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of formulations for buccal mucosal

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administration, to have looked in the art for other specific active agents suitable for spray formulations of liquid carriers, as taught by Fassberg et al, with reasonable expectations of successfully preparing suitable formulations for various therapies.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
May 11, 2005


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600